

Attorney Docket No.: DEX-0054  
Inventors: Robbins et al.  
Serial No.: 09/426,548  
Filing Date: October 22, 1999  
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#### REMARKS

Claims 1-3 are pending in the instant application. Claims 1-3 have been rejected. Claim 1 has been canceled. New claim 9 has been added. Claims 2 and 3 have been amended in light of the changes to claim 1 and 9. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Rejection of Claims 1-3 under 35 U.S.C. 112, first paragraph

Claims 1-3 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, has possession of the claimed invention. Specifically, the Examiner suggests that the recitation of GenBank Accession Nos. U07418 and U03911 finds neither literal nor figurative support in the specification.

These claims have also been rejected under 35 U.S.C. 112, first paragraph, for lack of enablement as the Examiner suggests that the claimed compositions are not described in the instant disclosure.

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In addition, claims 1-3 have been rejected under 35 U.S.C. 112, first paragraph, as the Examiner suggests that the claims encompass the entire gene and the skilled artisan cannot envision what other changes exist or can be made to the nucleic acid sequences encompassed by a variant gene.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 1 and added new claim 9. Claim 9 is drawn to an oligonucleotide probe to hMLH1 mutant 1, hMLH1 mutant 2, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant 3.

Claims 2 and 3, which depended from claim 1, have also been amended to be dependent from claim 9 and to conform with changes in language in new claim 9. Support for these amendments is provided throughout the specification and in particular at page 17, line 34, through page 20, line 5, and in the Examples Section.

Since the subject matter of new claim 9 and claims dependent therefrom is clearly described in the instant specification, the claims as amended meet the requirement under 35 U.S.C. 112, first paragraph, that the specification reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claim invention. Further, since the claims as amended are drawn to oligonucleotide probes for mutants acknowledged by the Examiner to be described in the specification,

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the claims as amended are also enabled by the instant specification. Finally, since the claims are now drawn to oligonucleotide probes to mutants acknowledged by the Examiner to be described in the specification, the claims as amended meet the written description requirements.

Withdrawal of all rejections under 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

## **II. Rejection of Claims 1-3 under 35 U.S.C. 112, second paragraph**

Claims 1-3 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that claim 1 is indefinite in the recitation of GenBank Accession Nos because GenBank represents a computer database that is subject to continuous updates and modifications. Further, the Examiner suggests that claim 1 is indefinite for the recitation of a "variant human MLH1 or MSH2 gene" because the genes have not been completely defined.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 1 and new claim 9 has been added. However, claim 9 contains neither the GenBank

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Accession Nos. nor the phrase "variant human MLH1 or MSH2 gene" which the Examiner suggests to be indefinite. Accordingly, withdrawal of this rejection is respectfully requested.

### III. Clarification of Finality of Office Action

The Office Action Summary page clearly indicates that this action is non-final. However, the Examiner indicates on page 8 of the Office Action that this action is Final. Since this is the first Office Action received since filing of a Request for Continued Prosecution and actual entry of the amendment relating to GenBank Accession Nos., and this response is Applicants' first opportunity to make amendments to the claims to address the Examiner's fully elucidated concerns relating to the GenBank Accession Nos., Applicants believe that in all fairness this action should be non-final. Thus, Applicants believe that the status of this Office Action is correctly identified on the Office Action Summary page as non-final. However, clarification of the status of this Office Action is respectfully requested.

### IV. Conclusion

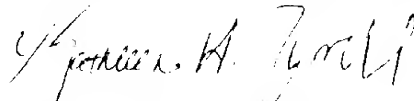
Applicants believe that the foregoing comprises a full and

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complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claim 1, without prejudice.

Please amend the claims as follows:

2. (amended) A method of diagnosing hereditary non-polyposis colorectal cancer in a patient comprising:

(a) obtaining a DNA or RNA sample from a patient; and

(b) screening the DNA or RNA sample ~~for the presence of~~  
~~a variant human MLH1 or MSH2 gene~~ with the oligonucleotide probe of  
claim  $\pm$  9, wherein ~~the presence of the variant gene~~ binding of the  
oligonucleotide probe to the DNA or RNA sample is indicative of  
hereditary non-polyposis colorectal cancer.

3. (amended) A method for predicting susceptibility of a patient to developing hereditary non-polyposis colorectal cancer comprising:

(a) obtaining a DNA or RNA sample from a patient: and

(b) screening the DNA or RNA sample ~~for the presence of~~  
~~a variant human MLH1 or MSH2 gene~~ with the oligonucleotide probe of  
claim  $\pm$  9, wherein ~~the presence of the variant gene~~ binding of the  
oligonucleotide probe to the DNA or RNA sample is indicative of a  
susceptibility to hereditary non-polyposis colorectal cancer.